COURAGE Chronicle

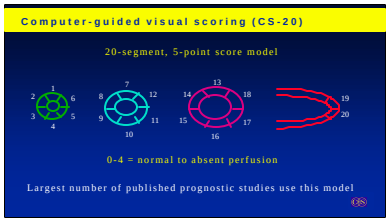
October 2000

Important Change to Nuclear Substudy II

The steering committee has approved an exciting change in Nuclear Substudy II (NSII) which is likely to enhance patient participation and increase the amount of clinically relevant information in the Substudy. NSII is designed to look at the effects of medical and interventional therapy on ischemic burden as determined by myocardial perfusion SPECT imaging in patients enrolled in the COURAGE trial.

The Change: The post-randomization interval for the repeat nuclear study will be 6 to 14 months (not the previous 2 to 4 months). The study will be performed on patients whose symptoms improve or remain unchanged. In patients with symptomatic worsening, nuclear studies are recommended at the time of worsening when feasible to help guide management decisions.

Studying the patients in the 6-to-14-months time frame will avoid the problem with re-stenosis and may give results which are more predictive of patients' long term outcomes. Additionally, this time frame is one in which clinicians are often interested in for assessing the extent of ischemia in patients undergoing medical or PCI therapy.



Inclusion Criteria: Patients must have moderate to severe ischemia measured as a summed difference score [SDS] of = 5 as indicated on the baseline stress gated sestamibi scan to be eligible for enrollment in NSII. Prior to entry into NSII, the extent of ischemia and the technical adequacy of the baseline study is subject to verification by the core laboratory. Adenosine stress is preferred, but not mandated, for this protocol. A post-randomization gated sestamibi scan will be performed with the same form of stress as used in the pre-randomizatio n study.

Medications During SPECT: At pre-randomization it is preferred, but not mandated, that patients be off all anti-ischemic medications during their SPECT scan so that the extent and severity of ischemia shown will be maximized. Since the goal of this substudy is to determine whether intensive medical therapy reduces the amount of ischemia, patients should be on their usual medication regimen prior to the follow-up SPECT.

Tc-99m Sestamibi and Adenosine: Tc-99m sestam ibi (Cardiolite) and adenosine (Adenoscan) will be provided for each patient entered into the substudy, in addition to a $300 payment for each study (prerandomization and post-randomization).

IRB/Ethics Approval: Your informed consent for NSII must reflect this change in the time of the repeat nuclear study (from 2 to 4 months in the previous submission to 6 to 14 months). Since this nuclear study at 6 to 14 months can be considered clinically indicated, a separate informed consent, as we have previously required, may not be needed. Instead, it may be advisable to include the potential of a repeat nuclear study at 6 to 14 months in your main informed consent for the overall trial, therefore eliminating the separate informed consent for NSII. Also note that this modification in your main informed consent will probably qualify for an expedited review by your IRB/Ethics Committee. If you already have an approved informed consent for NSII or have already submitted your IRB for Nuclear NSII, you may either make the appropriate change in the existing consent, or incorporate the repeat nuclear scan in the main informed consent and eliminate your separate consent for SNII. In addition, your institution may require a radiation safety approval since this protocol includes radioactive imaging agents. You may also want to include the risks of radiation exposure if a repeat nuclear study is done in the "Risks" section of your informed consent.

If you have any questions or you need more information, please call Tara Gurtler (phone: 310-423-4387) at the Cedars-Sinai Nuclear Core Lab.

Be sure to visit the DuPont booth at the AHA
to see how SPECT imaging is being used to evaluate COURAGE patients.

The One-Year Stress Test

The one-year and three-year stress tests are to be done *with the patient remaining on all prescribed medications* so that the effectiveness of the patient's therapy can be analyzed.

Co-Chairman has Moved!

William E. Boden, MD, Study Co-Chairman has resigned from the Syracuse Veteran's Affairs Medical Center. His new title and address are:

Director of Cardiology
Hartford Hospital
Hartford, CT 06102
Ph: (860) 545-2880
Fax: (860) 545-3168
E-mail: wboden@harthosp.org

The Co-Chairman's office will remain at the Syracuse VA Medical Center location until June, 2001. Please send all correspondence to Karen Potter and Gail Bonham at the Syracuse VA Medical Center as usual until further notice.

Welcome to our newest site

Hartford Hospital has joined the COURAGE Trial as an enrolling center. Welcome to PI, Francis Kiernan, MD and Coordinator, Debbie Murphy, RN!

Delayed PCI

If a patient's PCI must be scheduled for a later date, complete the baseline assessment at randomization.

COURAGE Chronicle

Please be sure to distribute copies of the COURAGE Chronicle to all coordinators and investigators associated with the trial.

PATIENT ENROLLMENT UPDATE

		To Date	Since Annual Meeting
671	Audie L. Murphy VAMC – San Antonio	81	46
202	London Health Sciences Centres	59	42
580	Houston VA Medical Center	40	20
È	***WEEK 69: TARGET ENROLLMENT per SITE:***	***40***	***22***
203	Montreal Heart Institute	39	27
506	Ann Arbor VA Medical Center	32	10
205	Queen Elizabeth II HSC	28	21
598	John C. McClellan VA – Little Rock	28	18
558	Durham VA Medical Center	28	9
209	Sunnybrook & Women's College HSC	27	21
630	New York VA Medical Center	24	20
306	Mayo Clinic—Rochester	23	15
200	Foothills Hospital	22	16
596	Lexington VA Medical Center	22	14
663	Seattle VA Medical Center	22	13
501	Albuquerque VA Medical Center	21	14
312	University of Michigan Medical Center	18	13
308	Mid America Heart Institute/Shawnee Mission	17	5
584	Iowa City VAMC/Univ. of Iowa Hospital	16	12
304	Emory University Hospital	16	9
312	University of Oklahoma	15	9
210	The Toronto Hospital	15	8
207	St. Paul's Hospital	14	12
212	Vancouver Hospital & Health Science Centre	13	13
626	Nashville VA Medical Center	12	8
204	St. Michael's Hospital	11	11
301	Boston Medical Center	11	9
211	University of Alberta Hospital	9	6
201	Hamilton General Hospital, McMaster Clinic	9	6
314	MIMA Century Research Associates	8	8
208	Sudbury Memorial Hospital	8	7
648	Portland VA Medical Center	6	6
626	Vanderbilt University Medical Center	3	3
316	Hartford Hospital	2	2
315	Southern CA Kaiser Permanente Medical Gr.	1	1
***	All Terminated Sites	21	7

Total Patients as of 10/20/2000: - 721

USING THE PENTABLET

The PENTABLET should be used at all times unless there are extenuating circumstances. The PENTABLET allows more accurate data collection and prevents the shifting to ECOR of an undue burden. If it is apparent that it will not be possible to use the PENTABLET to collect QOL data from a patient, please communicate this in advance to Cheryl Lewis so that she can discuss other options with you.

Before mailing a data diskette to ECOR, please back up the data that you have downloaded from your PENTABLET *onto another diskette or a different PC*.